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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,361	07/06/2006	Andreas Mroncz	MRONCZ ET AL-1 PCT	2483
25889	7590	09/22/2009	EXAMINER	
COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			TREYGER, ILYA Y	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,361	<b>Applicant(s)</b> MRONCZ ET AL.	
	<b>Examiner</b> ILYA Y. TREYGER	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-13 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/06/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-13 of the US Patent Application No. 10/585361 filed 07/06/2006 are presented for examination.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

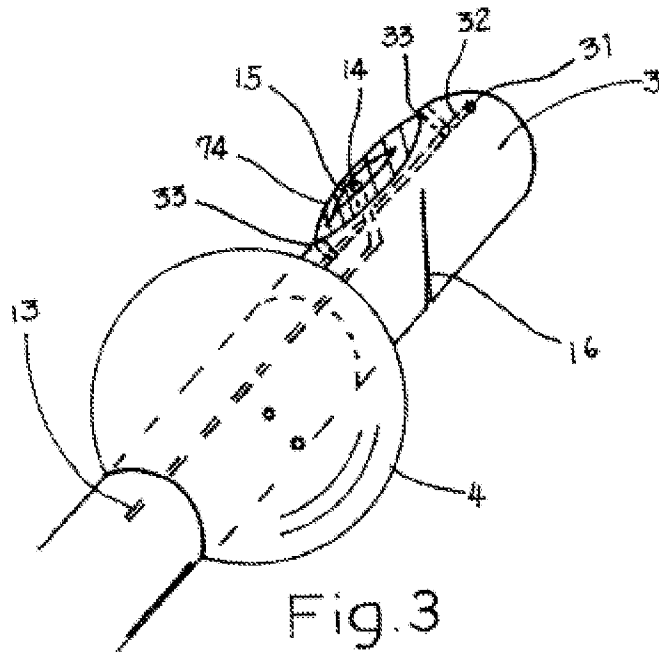
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 7, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Engel et al. (US 6,119,697).

4. In Re claim 1, Engel discloses a device for the treatment of human urinary incontinence with a catheter which can be inserted into the urethra and carries a balloon arrangement which can be filled with fluid to close off the urinary bladder and to hold the catheter in the lumen of the urethra. The fluid can be admitted to and discharged from this balloon arrangement via at least one closed channel running along the catheter wall which is closed off at the distal end of the catheter, and via a valve mounted at one proximal end section of the catheter in inserted condition. The length of the catheter is dimensioned such that its distal end in inserted condition lies within the urethra. A hydraulic actuating mechanism, also located in the lumen of the urinary bladder, is assigned to the self- closing valve. This hydraulic actuating mechanism can be hydraulically actuated by mechanical pressure exerted on an actuating balloon located at the distal end of the catheter which is filled with fluid and linked to the actuating mechanism via a connecting channel (See Abstract, lines 1-19).

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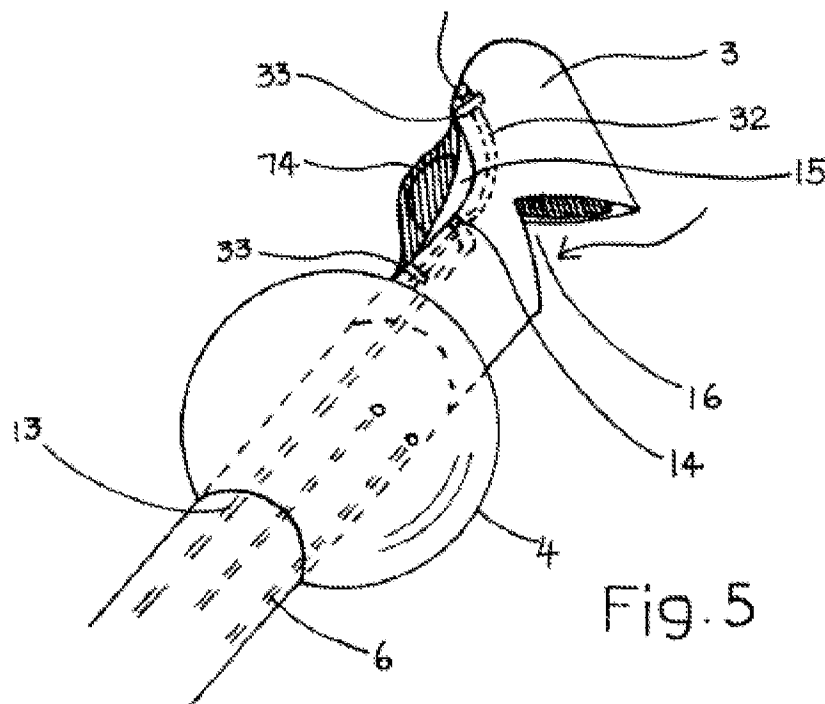
5. In Re claim 2, Engel discloses the device wherein the valve closure part has a conically shaped contact surface 3 (See Fig. 3).



6. In Re claims 3 and 4, since the conventionally known catheter referred by Engel is disclosed as made of elastic material (Col. 4, lines 39-40) all catheter elements are necessarily in the elastic connection. Since the valve element is disclosed as a part of the device (Col. 4, lines 57-59), the holder and joined elements (claim 4) are necessarily present.

7. In Re claims 7 and 8, Engel discloses the device wherein the activation channel connected with the activation balloon necessarily contains a pressure lumen separated by a separate valve 16 (Fig. 3) on the proximal end of the catheter and when this lumen is filled with the fluid the closure part 3 (Fig. 3) can be lifted up from the sealing contact (See Figs 3 and 5);

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wherein the valve necessarily allows in-flow into the lumen at the first, relatively high velocity, and permits back-flow from the lumen at a significantly lower second velocity (claim 8).

8. In Re claim 10, Engel discloses the device wherein the catheter is made of silicone (Col. 8, lines 21-23).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engel et al. (US 6,119,697).

13. In Re claim 5, Engel discloses the invention discussed above but does not expressly disclose the catheter wherein the holder element is formed on the closure part or on the proximal end segment of the catheter and is separately attached to the proximal end of the catheter or to the closure part.

It would have been obvious to one having ordinary skill in the art at the time the invention was made form the holder element on the one connected element or on the another connected element, since if two elements are being connected, there is only two options: to form the holder element on the one element or on the another. Consequently, if the holder element is formed on the first connected element it can be attached only to the second element.

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14. In Re claim 6, Engel discloses the invention discussed above but does not expressly disclose the device wherein the holder element is attached by the glued connection.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to attach the holder element by the glued connection in order to utilize the conventionally known method of connecting elements, since it was known in the art that elements can be connected via the glued connection.

15. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Engel et al. (US 6,119,697) in view of Lucas et al. (US 5,762,996).

Engel discloses the invention discussed above but does not expressly disclose the catheter wherein the balloons are made of silicone.

Lucas refers to conventionally known catheters having balloons made of silicone (Col. 1, lines 5-7 and 55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Engel with the silicone balloons, as taught by Lucas in order to employ balloons made of conventionally known materials to occlude the body tubular member (Col. 1, lines 58-59).

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and

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the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

16. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engel et al. (US 6,119,697) in view of Cioanta et al. (US 2004/0236365).

Engel discloses the invention discussed above but does not expressly disclose the catheter wherein the inflation liquid is oil.

Cioanta teaches the catheter wherein the inflation liquid is oil such as olive oil (claim 13) (page 9, [0099]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the catheter of Engel with the inflation liquid such as olive oil, as taught by Cioanta in order to utilize the conventionally known type of inflation liquid to reduce noxious effects (page 9, [0099], lines 7-9).



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***Allowable Subject Matter***

17. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is an examiner's statement of reasons for allowance: The prior art of record US 6,119,697, US 5989288, US 6355014 and US 5378238 fail to teach or suggest the catheter wherein the valve has a shaft having a passage opening in the pressure lumen.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5989288 disclose the Device for maintaining urinary continence. US 6355014 disclose the Low profile catheter valve. US 6855126 disclose the Conformable balloonless catheter. US 5378238 disclose the Innerless dilatation catheter with balloon stretch or manual valve. US 6090083 disclose the Low profile valve and balloon catheter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761